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TO: Commissioner Paul J. Cote, Jr. and Members of the Public Health Council

FROM: Paul I. Dreyer, Associate Commissioner

DATE: November 14, 2006 (Issued November 7, 2006)

RE: Request for Emergency Promulgation of Proposed Amendments to 105 CMR
150.000: Licensing of Long Term Care Facilities, Related to Employee Influenza
Vaccinations

Purpose and Background

The Department is proposing amendments to the long term care facility licensure regulations (105 CMR 150.000) to require long term care facilities to offer employees annual vaccination against the influenza virus. In an effort to lessen the health and economic impacts of the influenza virus on Massachusetts residents, one of the precautions that can be taken is vaccination against the influenza virus for health care workers.

Vaccination is the primary method for preventing influenza and its severe complications. In January 2005, a report prepared by the George Washington University School of Public Health and Health Services analyzed state immunization laws for staff and residents of long term care facilities (LTCFs). According to that report, 21 states had no law or regulation. Thirteen states had laws or regulations requiring long term care facilities to distribute influenza vaccine to their employees; 27 states required LTCFs to distribute influenza vaccines to their residents.¹ Although the Centers for Disease Control and Prevention (CDC) has recommended influenza vaccination for all health care workers since 1981, in 2005, the CDC's Advisory Committee on Immunization Practices emphasized in its recommendation that all health care workers should be vaccinated annually against influenza.

Extrapolating from national estimates, in any given year in Massachusetts 2600 residents are hospitalized and 800 residents die from complications of influenza. Again extrapolating from

¹ It should be noted that some states, including Massachusetts, offer the vaccine to LTCF residents without a regulatory requirement but consistent with the recommendation of the Centers for Disease Control and Prevention.

national estimates, the cost of a severe influenza season in Massachusetts can be as high as \$280 million. In addition to the direct medical cost of treating influenza, for each episode of influenza in healthy young adults, an average of 2.8 work days are lost. Studies have shown that influenza vaccine is cost-effective.

Epidemiological data suggest that health care workers can spread highly contagious influenza to patients in their care. Unvaccinated health care workers can be a key cause of influenza outbreaks in health care settings. There is broad recognition of the seriousness of this issue among health care-related professional organizations and government agencies (National Foundation for Infectious Diseases).

Estimated rates of influenza-associated pulmonary and circulatory-related deaths are highest among people ≥ 65 years of age. Deaths in older adults account for 90% of deaths attributed to pneumonia and influenza (CDC.MMWR 2005; 54(No.RR-8); 1-40).

It is currently estimated that fewer than 40 percent of health care workers are vaccinated against the influenza virus each year. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has recently approved a new infection control accreditation standard, to be implemented beginning January 1, 2007, for Critical Access Hospital, Hospital and Long Term Care accreditation programs. Under this standard these organizations must offer influenza vaccine to all staff, including volunteers, and licensed independent practitioners with close patient contact. However, JCAHO accreditation is voluntary and not all health care facilities seek this accreditation.

The Department already provides influenza vaccine for all long term care facility residents. To protect the employees and residents in long term care facilities and avoid influenza outbreaks as much as possible, the Department therefore is proposing through these amendments to require that all long term care facility employees be offered annual vaccination against the influenza virus. The proposed amendments also include language regarding the provision of information to every employee regarding the risks and benefits of the vaccine, recordkeeping, the opportunity for an employee to refuse vaccination and, in the case of such a refusal, documentation that the employee has received information about the vaccine and declined to receive the vaccine.

Next Steps

We are requesting emergency promulgation of these proposed amendments. With the Council's approval, the amendments will become effective immediately. Although the flu vaccine requirement will not be in effect until the 2007-8 flu season, as indicated in 105 CMR 150.002(D)(8)(a), emergency promulgation will allow long term care facilities to plan and in January 2007 order sufficient vaccine for the next flu season. The Department has worked closely with the LTCF industry in the development of these regulations and will conduct a public hearing/comment period on the amendments. Subsequent to consideration of comments received, staff will return to the Public Health Council with a recommendation concerning the amendments and final promulgation.

Amendments to 105 CMR 150.000 Regarding Health Care Worker Immunization
Against Influenza

105 CMR is amended by inserting the following new section as 105 CMR 150.002(D)(8):

(8) Requirement that employees be vaccinated against influenza virus.

- (a) No later than December 15, 2007 and annually thereafter, each facility shall ensure that every employee is vaccinated against influenza virus unless such employee declines vaccination in accordance with 105 CMR 150.002 (D) (8).
 - 1. For the purposes of 105 CMR 150.002 (D) (8), “employee” shall mean an individual employed (whether directly, by contract with another entity or as an independent contractor) by the facility, on a part-time or full-time basis, whether or not such individual provides direct patient care.
 - 2. For the purposes of 105 CMR 150.002 (D) (8), the requirement for “influenza vaccine” or “vaccination” means immunization by either influenza vaccine, inactivated or live, attenuated influenza vaccine.
- (b) Each facility shall provide every employee with information about the risks and benefits of influenza vaccine.
- (c) Each facility shall notify every employee of the influenza vaccination requirements of 105 CMR 150.002 (D) (8) and shall, at no cost to any employee, provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza unless such employee declines vaccination in accordance with 105 CMR 150.002(D) (8).
 - 1. Influenza vaccination and the documentation thereof shall take place no later than December 15 of each year.
 - 2. For an employee who is newly employed after December 1 but before April 1, and who cannot provide proof of current immunization against influenza, the facility shall provide or arrange for the vaccination within two weeks of the employee commencing employment.
- (d) Exceptions.
 - 1. A facility shall not require an employee to receive an influenza vaccine if:
 - a. the vaccine is medically contraindicated, which means that administration of influenza vaccine to that employee would likely be detrimental to the employee’s health;

- b. vaccination is against the employee's religious beliefs; or
- c. the employee refuses the vaccine.

2. An employee who does not get vaccinated for any reason shall sign a statement certifying that he or she received information about the risks and benefits of influenza vaccine.

(e) Unavailability of vaccine. A facility shall not be required to provide or arrange for influenza vaccination during such times that the vaccine is unavailable for purchase, shipment, or administration by a third party or when complying with an order of the Commissioner of Public Health which restricts the use of the vaccine. A facility shall obtain and administer influenza vaccine in accordance with 105 CMR 150.002(D) (8) as soon as vaccine becomes available.

(f) Documentation.

1. The facility shall require and maintain in each employee's personnel file a certificate of immunization for annual vaccination against influenza virus or any employee declination statement pursuant to 105 CMR 150.002 (D) (8).
2. Each facility shall maintain a central system to track the vaccination status of every employee.
3. If a facility is unable to provide or arrange for influenza vaccination for any employee, it shall document the reasons such vaccination could not be provided or arranged for.

105 CMR 150.000 is further amended by renumbering 105 CMR 150.002 (D)(8), (9) and (10) as 105 CMR 150.002 (D)(9), (10) and (11) respectively.